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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,450	12/14/2001	Guy Michael Miller	346392000900	1698
7590	11/23/2004		EXAMINER SPIVACK, PHYLLIS G	
Carol A Stratford Foley & Lardner Three Palo alto square 1 3000 el camino real suite 100 palo alto, CA 94306			ART UNIT 1614	PAPER NUMBER
DATE MAILED: 11/23/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,450

Applicant(s)

MILLER ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,9-23,33-38,42-47 and 51-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,9-23,33-38,42-47 and 51-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' Amendment and Reply filed August 12, 2004 are acknowledged. Claims 3, 5, 7, 8, 24-32, 39-41 and 48-50 are/were canceled. New claims 63-72 are presented. Accordingly, claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-72 are now under consideration.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The present claims are not directed to compositions.

In the last Office Action claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. It was asserted the recitation "a non-alpha tocopherol enriched tocopherol composition" renders the claims indefinite because the open language employed permits any other active ingredient including alpha-tocopherols.

Applicants argue the recitation "a non-alpha tocopherol enriched tocopherol composition" is defined in the specification and means a composition comprising 50% or greater of a tocopherol other than alpha tocopherol.

With the clear understanding that the claimed compositions may comprise alpha tocopherols in a concentration up to 50%, the rejection of record under 35 U.S.C 112, second paragraph, is withdrawn.

Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62 were rejected in the last Office Action under 35 U.S.C. 102(e) as being anticipated by Wechter, W.J., U.S. 2004/0058987. It was asserted Wechter teaches methods for treating and/or

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ameliorating the symptoms of a cerebral ischemic condition in a mammalian subject comprising administering a non-alpha tocopherol enriched tocopherol composition to reduce neuronal damage related to said cerebral condition.

Applicants argue Wechter does not teach cerebral ischemic conditions or amelioration of a symptom of neuronal damage associated with a cerebral ischemic condition. Further, Applicants urge the filing date of Wechter is later than both the filing date and the priority dates of the instant application because Wechter's specification does not support the claimed subject matter.

Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62 were rejected in the last Office Action under 35 U.S.C. 102(e) as being anticipated both by Wechter, W.J., U.S. US 2004/0058986. It was asserted Wechter teaches methods of treating and/or ameliorating the symptoms of a noncardiovascular tissue ischemic condition comprising administering a non-alpha tocopherol enriched tocopherol composition. As recited in claim 3, page 21, non-cardiovascular tissue ischemic conditions are spinal cord ischemia, liver ischemia, kidney ischemia, *inter alia*, in US 2004/0058986. It is the Examiner's position a reduction of neuronal damage would occur following treatment of ischemia in noncardiovascular tissues, such as the spinal cord.

Applicants argue Wechter does not teach non-cardiovascular tissue ischemia and the concept is introduced for the first time into the claims in US 2004/0058986. Further, Applicants urge the filing date of Wechter is later than both the filing date and the priority dates of the instant application because Wechter's specification does not support the claimed subject matter.

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In the last Office Action claims 1-64 and 98 were rejected under 35 U.S.C. 103 as being unpatentable over Wechter, W.J., US 2004/0029954. The claims encompassed in this rejection should have been claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62, as Applicants suggest. (The Examiner regrets the inadvertent recitation of claims of another co-pending application of the present inventive entity.) It was asserted Wechter broadly claims methods of treating any ischemic condition comprising administering a composition comprising tocopherols, at least 50% of which are γ -tocopherol. Examples of ischemic conditions are recited in the claims of US 2004/0029954, pages 21-22.

Applicants argue there is nothing in the reference that would suggest that its teachings of the various enumerated disease states might also be applicable to treating non-cardiovascular tissue ischemia. Further, Applicants urge the assertion that an improvement in blood supply to the brain would result in a reduction of neuronal damage associated with ischemia lacks basis in the specification or in objective reality.

A brief discussion in the Merck Manual is supplied to support the Examiner's position that an improvement in blood supply to the brain would reasonably result in a reduction of neuronal damage.

In response to Applicants' arguments to the three art rejections set forth in the last Office Action, it will be necessary to obtain and review all of the Wechter applications in the family of cases. Accordingly, the art rejections of record will be maintained, and extended to include new claims 63-72, until support or lack of support for the claims in the Wechter references can be established.

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The rejection in the last Office Action of claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 11-13, 22, 31-33, 42, 53-57 and 98 is maintained following Applicants' request to hold this rejection in abeyance.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The examiner can normally be reached Monday to Friday from 9:30 to 6 PM.

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If attempts to reach the examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at 571-272-0585. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phyllis G. Spivack
Primary Examiner
Art Unit 1614

November 19, 2004